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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

UNITED STATES OF AMERICA,)
Plaintiff,)
v.) Case No. 4:23-CR-380
SONNY SAGGAR, M.D., and RENITA BARRINGER,)
Defendants.)

<u>DEFENDANTS' REPLY IN SUPPORT OF</u> <u>MOTION TO STRIKE PORTIONS OF THE INDICTMENT</u>

As discussed below, the Government's effort to defend an invalid regulation falls short.

I. The Invalidity of the Regulation is Highly Relevant

The Government claims that, "[a]t trial, the United States will present evidence that Defendants' compliance with § 334.037 and its promulgating regulations was material to Missouri Medicaid's decision to reimburse claims." Doc. 64 at 5 (emphasis added). Yet, it argues that this case "has nothing to do with [the regulation's] validity under state law." *Id.* at 4. Defendants submit that if compliance with the regulation "was material to Missouri Medicaid's decision to reimburse," then the validity of the regulation is critically relevant. In fact, those are the words the Government uses – "Critically, § 334.037 provides that "[t]he collaborating physician shall determine and document the completion of at least a one-month period of time during which the [AP] shall practice with the collaborating physician continuously present'....

[T]he regulation at issue, 20 C.S.R. § 2150-2.240(1)(D), interprets § 334.037.7 by defining 'continuously present.'" *Id.* at 5 (emphasis added).

The Government continues: "[a]s the Indictment alleges, Missouri Medicaid required compliance with these provisions as a condition of payment." *Id.* But, that is Defendants' exact point – the Indictment wrongly alleges compliance with an invalid regulation is required. Medicaid cannot require compliance with an invalid regulation. Therefore, its validity is completely at issue. In attempting to refute the relevance of the regulation's invalidity, the Government argues, "even if 20 C.S.R. § 2150-2.240(1)(D) were invalid under state law, Medicaid was still entitled to rely on compliance with it as a condition of payment." *Id.* Unbelievably, the Government is arguing that Medicaid can issue improper, invalid and unenforceable regulations, and everyone needs to comply with them nevertheless – and failure to do so is a fraud! Not surprisingly, the Government cites no case law for this concept.

Moreover, Paragraph 32 of the Indictment specifically alleges that "[c]ontrary to the **legal** requirements regarding the use of APs, a collaborating physician was not continuously present at SLGH." (emphasis added). There can be no dispute that the Indictment is alleging that the regulation defining "continuously present" was a "legal requirement." The Government's Johnny-come-lately claim that the validity of the regulation is irrelevant, flies in the face of the allegation referring to it as a "legal requirement." If invalid, it cannot be a "legal requirement."

In an attempt to legitimize its argument, the Government claims that notwithstanding its potential invalidity, the regulation's "relevance goes directly to an element of the offense: materiality of the misrepresentation to Medicaid." Doc. 64 at 5-6. Yet, it fails to explain how failure to comply with an invalid and unenforceable regulation could be material to anything, let alone material to a fraud case. Such an argument flies in the face of common sense and the Indictment's own labeling of the regulation as a "legal requirement."

II. The Regulation is Invalid and a Nullity

It should first be noted that, contrary to the Government's assertion, Defendants' motion to strike does not rely on the issue of "delegated authority." Defendants are unsure how the Government could read such an argument into what Defendants submitted. Nevertheless, the three pages the Government devoted to that issue are irrelevant to Defendants' motion.

To repeat what Defendants said in their opening brief, under Missouri law, "[w]hile administrative regulations are entitled to a presumption of validity and may not be overruled except for weighty reasons, the rules or regulations of a state agency are invalid if they are beyond the scope of authority conferred upon the agency, or if they attempt to expand or modify statutes." Spurgeon v. Missouri Consol. Health Care Plan, 549 S.W.3d 465, 467 (Mo. App. 2018) (citing Union Elec. Co. v. Director of Revenue, 425 S.W.3d 118, 124-125 (Mo. Banc 2014)) (citations omitted) (emphasis added). See also, Circuit City Stores, Inc. v. Dir. of Revenue, 438 S.W.3d 397, 402 (Mo. 2014) (the agency's "regulation cannot enlarge the meaning of the statute beyond its terms."). The question being presented by Defendants is whether the regulations enlarged the meaning of the statute beyond its terms. Importantly, the Government offers no challenge to the application of this legal standard and does not dispute that a regulation which does attempt to "expand or modify" the statute is invalid. See Spurgeon, 549 S.W.3d at 467.

The regulation, 20 C.S.R. § 2150-2.240(1)(D), requires the collaborating physician to be "physically present and seeing each and every patient with the [AP] when said [AP] is seeing and/or treating a patient." (emphasis added). Where did the requirement that the collaborating doctor see "each and every patient with the [AP] when said [AP] is seeing and/or treating a patient," come from? No one knows, but it certainly is nowhere in the statute.

The Government concedes that "the 'ordinary meaning' of the phrase 'continuously present' makes . . . reference to 'location.'" Doc. 64 at 7. Defendants submit "location" cannot be understood to mean a specific room and conducting certain activity within the "location" without expanding the ordinary meaning of location. The regulation requires both physical presence and seeing each patient at the same time the AP does.

As noted previously, the Missouri Board of Registration for the Healing Arts has regulatory supervision over physician assistants, advanced practice nurses and assistant physicians. It has issued regulations as to all three groups of medical providers:

- 20 C.S.R. § 2150-2.240 Assistant Physician Collaborative Practice Agreements
 - (C) An assistant physician who desires to enter into a collaborative practice arrangement at a location where the collaborating physician is not continuously present shall practice together at the same location with the collaborating physician continuously present for a period of at least one (1) month before the collaborating assistant physician practices at a location where the collaborating physician is not present. During this one (1) month period, the collaborating physician must review ten percent (10%) of the assistant physicians' patient's records. It is the responsibility of the collaborating physician to determine and document the completion of the same location practice and records review as described above.
- 20 § 2150-5.100 Collaborative Practice Arrangements with Nurses
 (2)(C)An APRN [Advanced Practice Nurse] who desires to enter into a collaborative practice arrangement at a location where the collaborating physician is not continuously present shall practice together at the same location with the collaborating physician continuously present for a period of at least one (1) month before the collaborating APRN practices at a location where the collaborating physician is not present. It is the responsibility of the collaborating physician to determine and document the completion

of the same location practice described in the previous sentence.

20 § 2150-7.135 Physician Assistant Collaborative Practice Arrangements
(6) It is the responsibility of the collaborating physician to determine and document the completion of a one- (1-) month period of time during which the licensed physician assistant shall practice with a collaborating physician continuously present before practicing in a setting where a collaborating physician is not continuously present. The collaborating physician may determine what constitutes a one- (1-) month period.

Notwithstanding that all three regulations were revised as of 2022, and that all three are based off the language of the respective applicate statute (which each contain almost identical language),

only the regulation related to assistant physicians -APs - has a specific definition of "continuously present."

Of course, it is black letter law that the legislature's use of "continuously present" would indicate an intent for the same meaning to apply to all three statutory sections. Therefore, the simple question is, why did the MBRHA only promulgate a specific definition for assistant physicians? If the definition simply reflected what the statute called for, then just like for physician assistants and advanced practice nurses, no definition would be necessary. The MBRHA has given a definition to "continuously present" not applicable to the other mid-level providers who have the same statutory requirement.

Moreover, remembering that all three statutes call for the same training requirement, looking at both the assistant physician and the advanced practice nurse regulations tells us what the MBRHA actually understood the statutory language to mean. The last sentence of the two above-quoted regulations states, "It is the responsibility of the collaborating physician to determine and document the completion **of the same location practice** described in the previous sentence." (emphasis added). Clearly, it is a same location practice, not a same exam room practice. The statutes call for a location practice, but the definition of "continuously present" – only found in the assistant physician regulation – calls for an exam room practice, which is clearly different.

Subpart (C) of the assistant physician regulation clearly talks in terms of the broader term "location" rather than some concept of the same exam room — "a collaborative practice arrangement at a location where the collaborating physician is not continuously present . . . at the same location with the collaborating physician continuously present . . . before the collaborating assistant physician practices at a location where the collaborating physician is not present. . . document the completion of the same location practice" As reflected in Subsection

(C), there is no suggestion in the statute that instead of a location (i.e., an office building), to be continuously present meant to be in the same exam room seeing each and every patient while being seen by the AP.

In fact, even the Government slipped into treating the statute as addressing a question of location. In Paragraph 32 it alleges, "Contrary to the legal requirements regarding the use of APs, a collaborating physician was not continuously present <u>at SLGH</u>." (emphasis added). SLGH is most certainly a "location" versus a specific exam room where each patient is seen.

Notably, the first line of 20 C.S.R. § 2150-2.240(C) reads: "An assistant physician who desires to enter into a collaborative practice arrangement at a location where the collaborating physician is not continuously present...." It starts by referencing "a desire" to enter into an arrangement where the collaborating physician is not continuously present. If "continuously present" means "seeing each and every patient with the [AP] when said [AP] is seeing and/or treating a patient," then the premise of the regulation would be absurd. No assistant physician, and even more so, no collaborating physician would view both of them "seeing each and every patient with the [AP] when said [AP] is seeing and/or treating a patient" as ever a full-time alternative. The only way the creation of the assistant physicians would work for a medical facility is for the AP to be able to be in exam rooms separate from the collaborating doctor. So, it would be silly to talk in terms of a "desire" to do so. Therefore, that cannot be what the legislature meant by continuously present.

As discussed in Defendants' previous filing, the Board of Registration for the Healing Arts took a big loss in *State Bd. of Registration for the Healing Arts, Petitioner, vs. Robert B. Smith, M.D., Respondent*, Mo. Admin. 03-1609 HA (June 10, 2004). As is evident from the addition of subsection (D) regarding assistant physicians, the Board apparently reacted to its loss by adding a

new requirement for APs—i.e., presence within the exam room for each and every patient – when never imposed for other mid-level medical providers. If not an expansion of the statute, then why does the definition not apply to the other mid-level providers who operate under the same statutory language? The new addition was an obvious attempt to expand and modify the statute.

No state agency is ever allowed to "attempt to expand or modify statutes." *Spurgeon*, 549 S.W.3d at 467. When an agency does so, the regulation becomes a nullity. *Parmley v. Missouri Dental Bd.*, 719 S.W.2d 745, 755 (Mo. 1986) ("erroneous regulations are a nullity"). Therefore, the allegations that reference or rely on that statute, Paragraphs 10 and 32, should be stricken from the Indictment.

As the Eighth Circuit has said in multiple cases, a motion to strike surplusage from an indictment may be granted "where it is clear [that] the allegations contained therein are not relevant to the charge made <u>or</u> contain inflammatory and prejudicial matter." *United States v. Morales*, 813 F.3d 1058, 1066 (8th Cir. 2016) (emphasis added). An invalid regulation has to be irrelevant, and allegations of violating an invalid regulation have to be prejudicial. Paragraphs 10 and 32 are the very definition of "surplusage" under the Federal Rules. Each should be stricken from the Indictment.

To determine this issue, the Court merely needs to address a pure question of law: whether 20 C.S.R. § 2150-2.240(D) is null and void because it attempts to expand and modify the applicable statute, Mo. Rev. Stat. § 334.037.7. This is only a question of statutory interpretation. No questions of fact exist. Consequently, as the Court suggested, Defendants will agree with the Government that a hearing on this motion is unnecessary.

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Dated: November 14, 2023 Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on November 14, 2023, a copy of the foregoing was filed electronically via this Court's CM/ECF system, and therefore served on all parties of record.

/s/ James G. Martin
James G. Martin